UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/991,381	10/22/2001	William M. Adams	00013/01UTL	2660

26912 7590 08/06/2009

GOWLING LAFLEUR HENDERSON LLP
SUITE 1600, 1 FIRST CANADIAN PLACE
100 KING STREET WEST
TORONTO, ON M5X 1G5
CANADA

EXAMINER	
KOPPIKAR, VIVEK D	
ART UNIT	PAPER NUMBER
3686	

MAIL DATE	DELIVERY MODE
08/06/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/991,381	ADAMS, WILLIAM M.	
	Examiner	Art Unit	
	VIVEK D. KOPPIKAR	3686	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date. _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

1. Claims 1-38 have been examined in this application. This is a Final Office Action in response to the "Amendment" and "Remarks" filed on July 29, 2008 and June 16, 2009.

Claim Objections

2. Claim 11 is objected to because of the following informalities:

The term "prescriber" in line 4 should be "prescribers". Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-14 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The limitation "the token having been distributed by a drug dispense to the prescriber" does not have support in the specification and therefore seems to be new matter. Sections [0024], [0029], [0030], and [0033] discuss the aspect of the token being distributed to the prescriber however these sections do not specifically state the token is distributed to the prescriber by a drug dispenser.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-2, 4-7, 9-14, 15-20, 22, 24-27, 29-32, 34, 36-38 rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent Number 5,832,449 to Cunningham in view of US Patent Number 5,945,651 to Chorosinski.

(A) As per claim 1, Cunningham teaches a computer implemented method for tracking distribution of pharmaceutical drug samples prescribed by a prescriber to a prescribed patient (Cunningham: Col. 11, Ln. 53-Col. 12, Ln. 11),

comprising a step of adjudicating, at a health plan adjudication database system, a claim associated with the prescribed patient by a drug dispenser for the use of a token representative of a pharmaceutical drug sample (Cunningham: Figure 1—Item 12--Col. 10, Ln. 39-Col. 11, Ln. 40) (Note: In Cunningham, item 12 in Figure 1 represents a central computing station through which a pharmacy or drug dispenser attempts to adjudicate or validate the token or product trial media and the Office takes the position that it is within the scope of Cunningham that this central computer, represented by numeral 12, is part of a health plan adjudication database system because as Figure 1 illustrates, the central computing system is separate from the computer system of the drug dispensers (pharmacies) or the prescribers. Even assuming that the central computing station denoted by numeral 12 belongs to a pharmaceutical manufacturer, the central computing station can still be considered to be part of a health plan adjudication database system

because the pharmaceutical manufacturer which is administering the sample drug distribution program can be considered to be administering a health plan (the "health plan" comprising the drug sample distribution program) and adjudicating or approving the use of the tokens or product trial media prior to the dispensing of the pharmaceutical product sample.);

the token having been distributed by a drug dispenser to the prescriber (Cunningham: Figure 4A and Col. 7, Ln. 50-67)

the token is provided by the prescriber to the patient for obtaining the pharmaceutical drug sample from the drug dispenser (Cunningham: Col. 5, Ln. 40-45 and Col. 10, Ln. 21-26 and 39-50).

In Cunningham, the patient is not pre-identified, however, the Office takes the position that this feature is well known in the health care and pharmaceutical dispensing industry (i.e. to identify a patient on a prescription or a token to redeem to pharmaceutical sample) as is illustrated by Chorosinkski (Col. 7, Ln. 24-46). At the time of the invention, it would have been obvious for one of ordinary skill in the prescription dispensing industry to have modified the teachings of Cunningham with this aforementioned teachings from Chorosinski with the motivation of having a means of identifying a patient who redeems a pharmaceutical prescription or pharmaceutical sample, as recited in Chorosinksi (Col. 5, Ln. 24-46). One of ordinary skill in the art in the pharmaceutical dispensing industry would make this modification to Cunningham to ensure that prescription fraud does not take place and also to ensure that the prescription sample or prescription is dispensed only to the correct, identified patient since prescriptions or prescription samples can be dangerous if taken without authorization or approval for an authorized prescriber.

(B) As per claim 2, in Cunningham in view of Chorosinski, the step of adjudicating comprises steps of: receiving at the claim adjudication system a request for adjudication in a first predefined format from the drug dispenser; and sending to the drug dispenser an adjudication response in the predefined format in response to the request for adjudication (Cunningham: Figures 7A-7B and Col. 10, Ln. 39-50). (The Office takes the position that the procedure or algorithm set forth in the above quoted section of Cunningham and in the above quoted figures of Cunningham set forth a predefined format of sending a request for adjudication from the drug dispenser to the health plan adjudication database system and for sending to the drug dispenser an adjudication response in the predefined format in response to the request for adjudication.).

(C) As per claim 4, Cunningham in view of Chorosinski teaches that the steps of receiving and sending are performed using a communications network for communications between a plurality of drug dispensers and a plurality of adjudicators for the electronic processing of pharmacy claims (Cunningham: Figure 1 and Col. 4, Ln. 65-Col. 5, Ln. 45).

(D) As per claim 5, in Cunningham in view of Chorosinski the step of adjudicating further comprises the steps of: receiving information about tokens that are distributed; receiving information about the token from the drug dispenser; and processing the request to provide the adjudication response using the information about tokens that were distributed, the information about the tokens from the drug dispenser, and business logic related to the token (Cunningham: Col. 10, Ln. 21-50; Col. 11, Ln. 40-Col. 12, Ln. 11).

(D) As per claim 6, Cunningham in view of Chorosinski teaches that the step of adjudicating further comprises a step of receiving information about the prescribers to which tokens were distributed, wherein the information about the token received from the drug

dispenser comprises prescriber information, and the step of processing further comprises a step of comparing the information about the prescriber with the information about the prescribers to which tokens are distributed (Cunningham: Col. 11, Ln. 53-Col. 12, Ln. 25).

(G) As per claim 7, Cunningham in view of Chorosinski teaches that the step of adjudicating further comprises steps of storing token usage data related to the token, and periodically providing the token usage data to enable evaluation of a pharmaceutical drug sample distribution program (Cunningham: Col. 11, Ln, 40-Col. 12, Ln. 25).

(H) As per claim 9, Cunningham in view of Chorosinski teaches a step of entering information related to the token into a pharmacy benefit management system used for dispensing pharmaceutical drugs and for sending and receiving adjudication communications (Cunningham: Col. 11, Ln. 30-Col. 12, Ln. 25).

(I) As per claim 10, Cunningham in view of Chorosinski further comprises a step of distributing token for delivery to prescribers (Cunningham: Col. 4, Ln. 65-Col. 5, Ln. 62 and Col. 9, Ln. 13-16).

(J) As per claim 11, Cunningham in view of Chorosinski further comprises a step of storing token distribution data related to the tokens, the token distribution data including prescriber information to identify prescribers to whom the tokens were distributed (Cunningham: Col. 11, Ln. 40-52).

(K) As per claim 12, Cunningham in view of Chorosinski further comprises the steps of periodically receiving token usage data related to the token, the token usage data being generated and stored by the claim adjudication system, and correlating the token usage data with token distribution data (Cunningham: Col. 9, Ln. 13-16 and Col. 11, Ln. 30-Col. 12, Ln. 17).

(L) As per claim 13, Cunningham in view of Chorosinski further comprises a step of prescribing the pharmaceutical drug sample for a patient using the token (Cunningham: Col. 10, Ln. 22-27).

(M) As per claim 14, Cunningham in view of Chorosinski further comprises a step of accounting to the drug dispenser for the dispensing of the pharmaceutical drug sample (Cunningham: Col. 12, Ln. 4-11).

(N) As per claims 15-20, 22, 24-27, 29-32, 34 and 36-38 these claims are substantially similar to Claims 1-2, 4-7 and 9-14, and are therefore rejected on the same basis as these claims, which is set forth above.

7. Claims 3, 23, 28 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable Cunningham in view of Chorosinski as applied to Claim 2, 22, 27, 34, above, respectively, and in further view of US Patent Number 5,666,490 to Gillings.

(A) As per claim 3, Cunningham does not teach that the step of receiving and sending are performed in accordance with a protocol for electronic processing of pharmacy benefit claims, however, this feature is well known in the art as evidenced by Gillings (Claim 1, part (k)). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified Cunningham in view of Chorosinski with the aforementioned feature from Gillings with the motivation of improving the quality and integrity of the process of managing pharmaceutical data, as recited in Gillings (Col. 1, Ln. 65-Col. 2, Ln. 3).

(B) As per claims 23, 28 and 35, these claims repeat features previously addressed in the rejection of claims 1-14 and are rejected on the same basis.

8. Claim 8, 21 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cunningham in view of Chorosinkski, as applied to Claim 1, 15, 27, above, respectively, and in further view of US Patent Number 6,564,121 to Wallace.

(A) As per claim 8, Cunningham does not teach or suggest that the step of adjudicating further comprises a step of providing one or both formulary management services and drug utilization review services, however, this feature is taught by Wallace (Col. 10, Ln. 40-50 and Col. 28, Ln. 22-34). At the time of the invention, it would have been obvious for one of ordinary skill in the art to have modified the teachings of Cunningham in view of Chorosinski with the aforementioned teachings from Wallace with the motivation of having a means of providing a patient with a safe, automated, and low cost drug delivery system, as recited in Wallace (Col. 2, Ln. 8-15).

(B) As per claims 21 and 33, these claims are substantially similar to claim 8 and are therefore rejected on the same basis as claim 8, which is set forth above.

Response to Arguments

9. Applicant's arguments filed on June 16, 2009 have been fully considered but they are not persuasive. Applicants arguments will be addressed in sequential order as they were presented in the Remarks section.

(1) Applicant's argument that Cunningham does not disclose a pre-identified patient is moot in view of the new ground of rejection over the Chorosinski patent reference, set forth above.

(2) Applicants argue that the product trial media of Cunningham is not a token because a is defined as “something give or shown as a guarantee” and that the product trial

media of Cunningham is not a token provided by the prescriber to the patient because only after authentication of the product trial media is successfully completed at the pharmacy is a right to a drug sample created.

To respond to this argument, the Office would like to point out that just because a token or a right needs to be authenticated does not mean that it is not a right or a guarantee (to some product or right) or a token. For example, the right to vote is frequently referred to as a "right" by society, however, when one goes to vote on election day their identify must be verified or authenticated before they are eligible to vote. In a similar sense, the product trial media given out in Cunningham is a token because it gives the recipient a right or a guarantee to a pharmaceutical drug sample after authentication, therefore the product trial media given out by prescribers to patients in Cunningham can be considered a right (token) similar to how voting is considered a right . Furthermore, the applicants argue that in the applicant's instant invention, "no further validation is necessary, nor required, to perfect a right to a drug sample". To respond to this argument, the Office would like to point out that this above mentioned limitation is not in the claims so it has not been given patentable weight by the Office.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. If any attempt to reach the examiner by telephone is unsuccessful, the examiner's supervisor, Jerry O'Connor, can be reached at (571) 272-6787. The fax telephone numbers for this group are either (571) 273-8300 or (703) 872-9326 (for official communications including After Final communications labeled "Box AF").

Another resource that is available to applicants is the Patent Application Information Retrieval (PAIR). Information regarding the status of an application can be obtained from the (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAX. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, please feel free to contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sincerely,

/Vivek D Koppikar/

Primary Examiner, Art Unit 3686

August 3, 2009